IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 06-310 (GMS)
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION UNDER FED. R. CIV. P. 12(b)(6) TO DISMISS PLAINTIFF MERCK & CO., INC.'S FIRST AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

Dated: June 23, 2006

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INTRODUCTION

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") submits this brief in support of its motion under Fed. R. Civ. P. 12(b)(6) to dismiss plaintiff Merck & Co., Inc.'s ("Merck") First Amended Complaint (D.I. 9) for failure to state a claim upon which relief can be granted. Merck's amended complaint purports to plead a claim for "fraud on the court" and seeks to reopen the judgment in a patent infringement case that Merck lost in the Federal Circuit. Even accepting Merck's largely false allegations as true, it cannot prevail, and its amended complaint must be dismissed.

NATURE AND STAGE OF THE PROCEEDINGS

This action stems from an earlier litigation in this Court between the same parties. In that case, Teva USA had filed an amendment to an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic equivalent to Merck's Fosamax drug product, and Merck alleged that the use of that proposed product would infringe its U.S. Patent No. 5,994,329 ("the '329 patent"). That patent claims administering the compound alendronate (the active ingredient in Fosamax) once a week at a dosage strength seven times the daily dose. (D.I. 9 at ¶ 25.)

Merck sued to enforce the '329 patent. Teva USA stipulated to infringement, and following a bench trial, Judge Farnan found the asserted claims of the '329 patent not invalid and enforceable. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 288 F. Supp. 2d 601 (D. Del. 2003). (D.I. 10, Ex. F.) The Federal Circuit reversed, however, holding the asserted claims invalid as obvious over the prior art. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005). (D.I. 10, Ex. I.) The

Federal Circuit issued its mandate on April 28, 2005. On May 2, 2005, this Court entered judgment against Merck pursuant to the mandate.

More than a year later, on May 10, 2006, Merck filed this action against Teva USA under Fed R. Civ. P. 60(b), seeking (1) relief from the judgment entered by this Court, or (2) an injunction against Teva USA from asserting any estoppel based on the Federal Circuit's decision. (D.I. 9 at ¶¶ 68, 72.) In response, on May 31, 2006, Teva USA filed a motion under Fed. R. Civ. P. 12(b)(6) to dismiss Merck's initial complaint for failure to state a claim upon which relief can be granted. (D.I. 6.) Merck then filed an amended complaint on June 9, 2006. (D.I. 9.) Teva USA submits this motion under Fed. R. Civ. P. 12(b)(6) to dismiss Merck's amended complaint in lieu of an answer.

SUMMARY OF ARGUMENT

To obtain relief from the Federal Circuit's judgment in under Rule 60(b), Merck must prove that Teva USA committed "fraud upon the court." *Herring v. United States*, 424 F.3d 384, 389 (3d Cir. 2005). In this circuit, such a showing requires proof of an intentional fraud by an officer of the court, directed to the court, and that the court was, in fact, deceived. *Id.* at 390. Even if they are assumed to be true, the facts Merck alleges cannot support such a claim. Merck alleges that Teva USA committed "fraud" by criticizing at trial experiments disclosed in Merck's '329 patent that involved the administration of alendronate to beagles, while at the same time not producing in discovery certain documents, in particular, U.S. Patent Provisional App. No. 60/433,685 ("the '685 application") (D.I. 10, Ex. J), filed by Teva USA's Israeli parent corporation, Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), which was not a party to the case. Of course, Merck's complaint does not even get out of the starting gate because the '685

application was not filed until December 16, 2002 (D.I. 9 at ¶ 43), almost three months after the close of fact discovery on September 20, 2002 (Rule 16 Scheduling Order, attached hereto as Ex. A at 1).[1] Merck does not explain how a document that did not exist until after the close of discovery could have been concealed. In any event, the '685 application describes an entirely different type of preclinical study from that described in the '329 patent. The only common denominator is that both studies involve administration of alendronate to beagles. As near as Teva USA can discern, Merck's theory is that Teva USA's original criticism was not a criticism of Merck's experimental design, but instead was a blanket indictment of the use of beagles, and its later employment of the same species and breed in an unrelated context somehow impeaches that criticism. Since this impeachment allegedly was not available to Merck at trial, the Federal Circuit[2] was unable to appreciate the profound nature of Merck's beagle experiments and discounted them. Finally, according to Merck, if only the Federal Circuit had known the full story of Merck's beagles, it would have held the patent claims valid instead of invalid.

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[1] Teva USA's reference to this Court's Rule 16 Scheduling Order here does not convert this Rule 12(b)(6) motion into a motion for summary judgment. *Herring v. United States*, No. 03-CV-5500, 2004 U.S. Dist LEXIS 1854, at *23 (E.D. Pa Sept. 10, 2004) (The Third Circuit and "[m]any other courts have considered matters of public record in ruling on a motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6) without converting the motion to one for summary judgment.").

[2] Although Merck contends that the district court was deceived, it does not explain how that deception can be reconciled with the fact that the court ruled in Merck's favor. *See* 288 F. Supp. 2d 601. (D.I. 10, Ex. F.)

Assuming for the purposes of this motion that Teva Ltd.'s statements about its own beagle experiments in fact contradict Teva USA's criticism during the litigation of Merck's beagle studies (which they do not), and that Teva USA was obligated to produce the studies to Merck but chose not to (which is not true), Teva USA's actions cannot, as a matter of law, be found to constitute "fraud on the court." Merck does not allege facts showing that Teva USA or its attorneys committed a fraud, and it does not allege facts showing that any fraud was intentionally directed to the district court (or any appellate court), or that the district court (or any appellate court) was deceived. Finally, the complaint itself shows that the bogus impeachment argument was available to Merck in the district court and the Federal Circuit, but Merck did not make it. Accordingly, because Merck's complaint does not state a claim upon which relief can be granted, it should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

STATEMENT OF FACTS

Although for purposes of this motion Teva USA will concede the facts of the complaint, that complaint is nevertheless replete with falsehoods and half truths. Exposing merely a few of them provides some insight into the nature of Merck's tactics.

First, Merck's entire complaint rests on the allegation that Teva USA did not provide discovery that it was obligated to provide. Merck relies on the Requests for Production ("RFP") that it served on Teva USA, the only defendant in the case. In particular, Merck relies on RFP 49, in which it requested "[a]ll documents and things relating to the research and development of alendronate and alendronate formulations or any other pharmaceutically active bisphosphonate and its formulations." (D.I. 9 at ¶ 20; D.I. 10, Ex. B at 17.) As Merck's complaint states, its RFPs sought to include Teva Ltd.

in the definition of "Teva," notwithstanding that Teva Ltd. was not a party, and had never been served with any sort of judicial process. (D.I. 9 at ¶ 21; D.I. 10, Ex. B at 4, definition I.)

Although Merck quotes freely from its own RFPs and argues that Teva USA failed to produce the documents they called for, Merck inexcusably did not include Teva USA's responses and objections to those requests. (Those responses were attached to Merck's motion to compel as Exhibit A, and Merck's motion along with Exhibit A to the motion is attached hereto as Exhibit B.)[3] In fact, Teva USA made two objections, each of which made clear that Teva USA was not undertaking to search for documents such as the '685 application, even had it existed. First, Teva USA objected to the RFPs to the extent that they called for documents from any entities other than Teva USA, and affirmatively committed to producing documents *only* from that entity:

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[3] The attachment of Merck's motion to compel and Teva USA's responses do not require conversion of this Rule 12(b)(6) motion into a summary judgment motion because Merck explicitly relies on its motion to compel, for example, in paragraphs 22, 23, 24, and 54 of its complaint. *In re Burlington Coat Factory Securities Litigation*, 114 F.3d 1410, 1426 (3d Cir. 1997) ("document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment") (citations omitted). This Court may therefore consider Teva USA's responses, which are part of Merck's motion to compel. *Pension Benefits Guaranty Corp. v. White Consolidated Industries, Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) ("[A] court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document. Otherwise, a plaintiff with a legally deficient claim could survive a motion to dismiss simply by failing to attach a dispositive document upon which it relied.") (citations omitted).

> Teva [USA][4] objects to definition I as overly broad to the extent it includes entities beyond Teva Pharmaceuticals, USA. For purposes of the document request, responsive documents in the possession, custody or control of Teva Pharmaceuticals, USA will be produced.

(Ex. B at Ex. A, 5.) The '685 application upon which Merck bases its complaint was filed by and is assigned to Teva Ltd., not Teva USA, and thus falls outside the scope of documents that Teva USA undertook to search for and produce. On its face, the patent application makes clear that the work was carried out in Israel, by Israelis, and not in the United States by anyone connected to Teva USA. (D.I. 10, Ex. J at 1.) Merck could not have overlooked Teva USA's objection at the time. If Merck disagreed with the appropriateness of that limitation, it was free to challenge it, either informally or by application to this Court. In addition, Merck could not have overlooked that objection when it filed its complaint in this case. Nevertheless, for the transparent purpose of misleading the Court, Merck did not include it in its complaint.

Another limitation that Merck knew about and could not have overlooked was Teva USA's objection to producing any documents relating to subjects other that the development of the once-weekly alendronate dosage forms that were the subject of Teva USA's ANDA:

> Teva objects to each document request to the extent it seeks the identification or production of documents relating to any bisphosphonate other than the weekly dose forms of alendronate that are the subject of Teva's October 23, 2000 and August 20, 2001 amendments to No. 75-710.

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[4] In its responses to Merck's RFP's, Teva USA made clear that it was using the term "Teva" to refer only to "Teva Pharmaceuticals USA, Inc."

(*Id.*) In other words, Teva USA informed Merck that it would only produce documents concerning the particular tablets that were the subject of Teva USA's ANDA. Merck does not allege that the '685 application would have met that criterion had it existed. Instead, the '685 application is directed to a highly experimental dosing regimen in which a vitamin D compound is administered to the patient first, and the alendronate tablet is administered later. The purpose of this regimen is to improve the "bioavailability" of the alendronate, *i.e.*, the amount of drug that the body actually absorbs. (D.I. 9 at ¶ 40, 44.)

Teva USA carried this objection over specifically to RFP 49, informing Merck that it would only produce documents relating to the weekly alendronate products that are the subject of ANDA No. 75-710, and even then only documents relevant to the issues in the lawsuit:

> Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to the General Objections, responsive documents relating to the weekly alendronate product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

(Ex. B at Ex. A, 24.) Merck never challenged this objection, either informally or by seeking judicial relief. Having accepted Teva USA's undertaking on the scope of the documents it would endeavor to produce, Merck cannot legitimately complain about the non-production of documents outside that undertaking.

Not only did Merck know that Teva USA would not search for and produce documents such as the '685 application, Merck knows that the beagle experiments disclosed in the '685 application are not in any way inconsistent with Teva USA's litigation arguments about Merck's beagle experiments as described in the '329 patent.

The experiments have a completely different purpose and design, and a criticism of one is not an indictment of the other or of beagle experiments in general.

The '329 patent discloses a series of experiments apparently designed to examine the toxic effect of alendronate on the esophagi of beagles. In these experiments, the beagles were anesthetized, laid prone, and their esophagi bathed in solutions of alendronate for half an hour. (D.I. 10, Ex. A at col. 14, ll. 52-55.) The beagles were then killed and the esophagus of each animal removed for microscopic examination for ulceration and other damage. (*Id.* at col. 15, ll. 42-46.) Of course, alendronate is not administered to humans in this way. It is given as tablets, and Merck provides a complicated set of dosing instructions to patients and doctors to ensure minimal exposure of alendronate to the esophageal tissues. Those measures include taking the tablets before eating anything, drinking a full glass of water and remaining upright for half an hour after administration. 288 F. Supp. 2d at 628. (D.I. 10, Ex. F at 628.)

At trial, Teva USA pointed out the obvious fact that the beagle experiments did not model human clinical experience. Teva USA argued that the experiments were therefore not relevant to the asserted claims of the '329 patent. (D.I. 9 at ¶ 29; D.I. 10, Ex. D at 45-46.) Teva USA's argument was easy to make, since it relied primarily on the testimony of Merck's scientists and experts, who agreed with Teva USA that the beagle experiments in the '329 patent were not relevant to human clinical experience with the administration of that drug. (*Id.*)

The studies in the '685 application are completely different from those in the '329 patent; they involved, *inter alia*, the administration of alendronate tablets to unanesthetized, fasted beagle dogs, followed by detection of alendronate in their urine to

determine the bioavailability of the drug. (D.I. 10, Ex. J at 8.) The purpose of the study – to determine if the "pre-dosing" of another compound improves alendronate bioavailability – is completely different, as is the methodology – measuring alendronate in the dog's urine instead of killing the dog and examining its esophagus for injury.

Merck's complaint itself makes clear that '685 application is not material. Teva Ltd. owns U.S. Patent No. 6,476,006 ("the '006 patent"), which describes a tablet construction for certain drugs, including alendronate. (D.I. 10, Ex. K at Ex. A.) It includes as Example 13 a discussion of the same type of study as Merck claims was "concealed" by the non-production of the '685 application. (*Id.* at col. 14, ll. 15-22.) Specifically, Example 13 describes a study involving beagles in which the dogs were administered the claimed tablets, their urine was collected, and the bioavailability (area under the curve or "AUC") determined:

> Tablets from example 11 were administered to 3 beagle dogs in a crossover design versus an immediate release alendronate formulation. Urine samples were collected for 48 hours and an overall AUC for alendronate was determined.

(D.I. 10, Ex. K at Ex. A, col. 14, ll. 16-24.) Merck successfully moved to add the '006 patent to the trial record, and referred to it at length in its post-trial reply brief and on appeal. However, Merck never mentioned Example 13, and never made an argument that the '006 patent was somehow inconsistent with Teva USA's criticism of Merck's beagle experiments. Thus, the same argument that Merck says Teva USA concealed was available all along, yet Merck never made it. That it did not demonstrates that the argument is bogus, and has been concocted for an illegitimate purpose.

Merck's complaint is transparently defective, and its defects become even more apparent under even a cursory examination of the underlying record. Merck's reasons for

bringing such a case are likewise clear: to delay and prejudice another case between the parties. Merck's complaint refers to the pending case between the parties that involves the drug substance risedronate, another compound in the same class as alendronate, which is prescribed for the same indications. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 04-939 (GMS). (D.I. 9 at ¶¶ 37-38.) This case is set for trial August 28, 2006. Although Merck does not sell risedronate, it has licensed Procter & Gamble ("P&G") to do so under Merck's once-weekly patents, including claims of the '329 patent that were not asserted in the alendronate case and that therefore have not yet been declared invalid. Merck receives substantial royalties from P&G, and those royalties will immediately cease if Merck loses the pending case. That outcome is likely, since the issues largely overlap. In addition, if Teva USA goes to market with generic once-weekly risedronate tablets, it will compete with Merck's Fosamax on the basis of price, something that P&G does not do. Thus, Merck has every incentive to delay the resolution of the pending case, and this complaint is a transparent attempt to do so.[5]

ARGUMENT

I. THE 12(b)(6) STANDARD

Under Fed. R. Civ. P. 12(b)(6), a complaint should be dismissed for failure to state a claim upon which relief may be granted if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). Although the Court must accept as

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[5] Merck's tactic did not succeed. The Court recently denied Merck's motion to

true all factual allegations in the complaint and draw all reasonable inferences in favor of the plaintiff, a "legal conclusion couched as a factual allegation" is given no presumption of truthfulness. *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

Further, "[w]hen allegations contained within the complaint are contradicted by documents attached to the complaint, the documents control, and the Court need not accept the allegations contained within the complaint as true." *Rozsa v. May Davis Group Inc.*, 187 F. Supp. 2d 123, 128 (S.D.N.Y. 2002). *See also Perkins v. Silverstein*, 939 F.2d 463, 469 n.4 (7th Cir. 1991) ("In determining the sufficiency of the complaint we must rely on the exhibits whenever the allegations of the complaint are materially inconsistent with those exhibits."); *Herring v. United States*, No. 03-CV-5500, 2004 U.S. Dist LEXIS 1854, at *25 (E.D. Pa Sept. 10, 2004) ("this Court will examine those facts that, in addition to averments in the complaint, exhibits, and the accident investigation report, the public record now unearths").

A claim may be dismissed when the facts alleged and the reasonable inferences drawn from those facts are legally insufficient to support the relief sought. *Herring*, 2004 U.S. Dist LEXIS 1854, at *8 (citing *Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 179 (3d Cir. 1988)). As the foregoing discussion makes clear, Merck's factual statements are false, unsupported, and contradicted by the facts contained in the exhibits attached to the complaint as well as those in the exhibits Merck failed to include but are nonetheless properly attached here; the Court need not accept Merck's false and

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reopen discovery in the risedronate case and to stay it pending the resolution of this case.

unsupported facts. Nevertheless, even if the complaint is true, it fails to state a claim that could support the relief Merck seeks.

II. MERCK'S COMPLAINT FAILS TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

A. To Avoid Dismissal Merck Must State Facts Demonstrating that Teva USA Committed "Fraud Upon the Court"

A party may bring a motion to seek relief from a judgment pursuant to Fed. R. Civ. P. 60(b) under certain circumstances:

> On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; (4) the judgment is void; (5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment. The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) *not more than one year after the judgment*, order, or proceeding was entered or taken . . . .

Fed R. Civ. P. 60(b) (emphasis added). For example, a party may seek relief from a judgment by filing a motion under Rule 60(b)(3) alleging "fraud . . . , misrepresentation, or other misconduct of an adverse party" (called "fraud between the parties") within one year from the date of judgment. *Id.* After the one-year period expires, under what has been referred to as the "savings clause" of Rule 60(b), a party may bring "an *independent action* to relieve a party from a judgment, order, or proceeding, . . . or to set aside a judgment for *fraud upon the court*." *Id.* (emphasis added). Merck seeks relief under this latter provision of Rule 60(b). Thus, unlike a motion brought within the year, an independent action must be based on a "fraud upon the court."

The "fraud upon the court" standard that must be met to support an independent action under Rule 60(b) is "narrower in scope" than "fraud between the parties" which will suffice to support a Rule 60(b)(3) motion filed within one year of judgment. *Gleason v. Jandrucko*, 860 F.2d 556, 558 (2d Cir. 1988) ("[T]he type of fraud necessary to sustain an independent action attacking the finality of a judgment is narrower in scope than that which is sufficient by timely motion."). Thus, Merck must prove more than a fraud on Merck. Independent actions are reserved for situations where a "grave miscarriage of justice" has occurred. *United States v. Beggerly*, 524 U.S. 38, 47 (1998). As the Third Circuit has explained:

> Actions for fraud upon the court are so rare that this Court has not previously had the occasion to articulate a legal definition of the concept. The concept of fraud upon the court challenges the very principle upon which our judicial system is based: the finality of a judgment. The presumption against the reopening of a case that has gone through the appellate process all the way to the United States Supreme Court and reached final judgment must be not just a high hurdle to climb but a steep cliff-face to scale.

Herring v. United States, 424 F.3d at 386.

The Third Circuit has articulated a demanding standard for determining whether a fraud upon the court has occurred that will support an independent action under Rule 60(b). To obtain relief, a party must prove: (1) an intentional fraud; (2) by an officer of the court; (3) which is directed to the court; and (4) that in fact deceives the court. *Id.* Further, the Third Circuit agrees with other circuits that a "fraud upon the court" requires the most egregious conduct directed to the court itself, and must be supported by clear and convincing evidence. *Id.* at 387.

B. Merck's Allegations Fail to State a Claim for "Fraud Upon the Court"

1. Merck Alleges that Teva USA "Withheld" Patent Applications, But Teva USA Could Not Have "Withheld" Documents that Did Not Exist

Merck complains that Teva USA "withheld highly relevant discovery, including its own patent applications" such as the '685 application, the '006 patent, and PCT patent application WO 03/057/136 ("the '136 application"). (D.I. 9 at ¶¶ 2, 40, 55-56.) Setting aside the '006 patent, which Merck admittedly had during the pendency of the prior litigation, the '685 and '136 applications did not exist until after Teva USA's responses were served April 19, 2002 (Ex. B at Ex. A, 30), and after the close of fact discovery on September 20, 2002. (Ex. A at 1.) The '685 application was not filed until December 16, 2002 (D.I. 9 at ¶ 43), and the '136 application was not filed until November 12, 2002 (D.I. 10, Ex. L at Ex. A, 1), well after Teva USA's obligations to produce documents had ended.[6] *See Kingsway Financial Services, Inc. v. Pricewaterhouse-Coopers LLP*, No. 03 Civ. 5560, 2006 U.S. Dist. LEXIS 28645, at *5-6 (S.D.N.Y. May 8, 2006) (party not required to produce document created after service of written response to document requests). Merck fails to explain how Teva USA could have "withheld" such documents that did not exist until after the close of discovery.

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[6] Although Merck's complaint mentions international patent application WO 2004/053235 ("the '235 application") (D.I. 9 at ¶¶ 44-47), Merck does not and cannot claim that Teva USA withheld the '235 application, as it was not filed until December 13, 2003 (D.I. 9 at ¶ 44), more than one year after the close of discovery and nine months after trial (Ex. A at 1, 3).

2. Merck's Allegations that Teva USA Withheld Documents Describing Beagle Studies Fail to State a Claim for "Fraud Upon the Court"

Setting aside the fact the "withheld" documents did not exist, Merck's allegations that Teva USA withheld documents from Merck that Merck believed to be relevant, while falsely representing that all such documents had been provided does not constitute "fraud upon the court." Although Merck alleges that it requested such documents, it nowhere alleges that Teva USA represented that it would produce them. Merck cannot make that allegation, because Merck knows that Teva USA not only never undertook to produce such materials; it in fact interposed timely objections to doing so (Ex. B at Ex. A), which Merck never challenged. Although Merck alleges that it filed a motion to compel (D.I. 9 at ¶ 22), that motion to compel never mentions RFP 49, the request on which Merck premises its entire complaint. (*See* Ex. B.) Likewise, the Kenyon letter Merck cites (D.I. 10, Ex. C), responds to Merck's motion to compel, and has nothing to do with RFP 49.

Assuming that the withheld documents were relevant (which they were not), and giving Merck's complaint the most charitable reading, at most Merck has stated facts demonstrating that Teva USA's action hindered Merck's ability to make a factual argument – that its beagle studies were more consequential than Teva USA asserted. Making false statements to Merck that undercut Merck's ability to argue about a factual issue in the case is at best a fraud on Merck – not on a court – that is, a so-called "fraud between the parties." This "deprivation" is not an injury to the Court or to the Court's function, but instead an injury only to Merck. A fraud between the parties cannot support relief from the judgment in an independent action under Rule 60(b).

Furthermore, where, as here, the alleged fraud is directed to the adverse party and could have been uncovered through that party's diligence, it does not work a grave miscarriage of justice and cannot justify reopening the judgment. *Appling v. Orrick, Harrington & Sutcliffe*, 340 F.3d 769, 780 (9th Cir. 2003). *See also Broyhill Furniture Indus., Inc. v. Craftmaster Furniture Corp.*, 12 F.3d 1080, 1085-86 (Fed. Cir. 1993) ("Fraud upon the court is thus typically confined to the most egregious cases, such as bribery of a judge or juror, or improper influence exerted on the court by an attorney, in which the integrity of the court and its ability to function impartially is directly impinged.") (citations omitted); *Gleason*, 860 F.2d at 559 ("Indeed, 'fraud upon the court' as distinguished from fraud on an adverse party is limited to fraud which seriously affects the integrity of the normal process of adjudication.").

Here, Teva USA's "fraud" could have been uncovered by Merck's diligence. For example, Merck could have challenged Teva USA's objections to its RFPs. Merck was unequivocally on notice through Teva USA's objections that it would not produce documents from Teva Ltd. in Israel or documents that related to products other than the specific weekly products identified in the ANDA. Once Teva USA objected to Merck's RFP's and the definitions stated therein, it was incumbent on Merck to challenge those objections. *Clinchfield Railroad Co. v. Lynch,* 700 F.2d 126, 132 n.10 (4th Cir. 1983) ("Once a party registers, by way of a timely response, an objection to a discovery request, 'the initiative rests with the party seeking their production to move for an order compelling it.'" (citing 4A James Wm. Moore *et al.*, Moore's Federal Practice ¶ 34.05[2] (2d ed. 1982)). Merck never challenged Teva USA's objections, and all of the materials that it now claims were improperly withheld are covered by them. Merck's allegations

that Teva USA withheld certain patents and patent applications do not amount to "fraud upon the court" and cannot support an independent action under Rule 60(b). *Appling*, 340 F.3d at 780; *Gleason*, 860 F.2d at 559.

Examples of situations in which an alleged "fraud" has not amounted to "fraud on the court" demonstrate why Merck's complaint, even if it states a claim for fraud, is insufficient. In *Beggerly*, the Supreme Court held that the government's failure to furnish relevant information and to make a thorough search of its records and make a full disclosure to the Court did not rise to a fraud upon the court that could support an independent action under Rule 60(b) for relief from a judgment. *Beggerly*, 524 U.S. at 46-47. In essence, that is all that Merck is pleading here – a failure by Teva USA to make a thorough search and disclose relevant documents. In *Gleason*, the Second Circuit found that perjury committed by a witness and withholding relevant evidence did not rise to the level of fraud upon the court that would sustain a separate action for relief from a prior judgment. *Gleason*, 860 F.2d at 557, 560. Merck nowhere alleges that any Teva USA witness committed a criminal act or was suborned to do so. In *Broyhill*, the Federal Circuit held that enforcing a patent obtained through inequitable conduct (where the patent was obtained by knowingly withholding material prior art from the Patent Office) "does not alone constitute one of 'the more egregious form of subversion of the legal process . . .'" and was thus not fraud upon the court. *Broyhill*, 12 F.3d at 1086-87 (citations omitted). In *Appling*, the Ninth Circuit concluded that non-disclosure or perjury by a party or a witness, does not, but itself, amount to fraud upon the court. *Appling*, 340 F.3d at 780. Again, Merck alleges a failure to provide discovery, not anything as fundamental an attack on the court's function as perjury.

Merck does not allege that Teva USA's lawyers created false documents for presentation to the Court or a government agency or that they suborned perjury, or the like. *See, e.g., Broyhill*, 12 F.3d at 1085-86. Instead, Merck alleges that Teva USA withheld documents concerning a beagle study that was not conducted in the same manner as the studies in the '329 patent and which Teva USA told Merck during the litigation it would not be producing. Teva USA's actions, which, even according to Merck, are orders of magnitude less egregious than the actions alleged in *Beggerly* (withholding relevant evidence), *Gleason* (perjury and withholding relevant evidence), and *Broyhill* (withholding material prior art from the Patent Office and enforcing a patent obtained through inequitable conduct) that were held *not* to constitute fraud on the court.

3. Merck's Allegations that Teva USA Made Misrepresentations to this Court and the Federal Circuit Fail to State a Claim for "Fraud Upon the Court"

Further, Merck fails to allege any *facts* showing that any fraud was intentionally directed to the district court or the Federal Circuit. All Merck does is allege repeatedly that Teva USA made "false representations" with "intent to deceive" the district court and the Federal Circuit by withholding the '685 application. (*See, e.g.*, D.I. 9 at ¶¶ 50-54, 59.) This Court, however, need not accept as true Merck's conclusory allegations that any statement is "false." *Papasan*, 478 U.S. at 286; *General Motors Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 333 (3d Cir. 2001) ("Conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss. While facts must be accepted as alleged, this does not automatically extend to bald assertions, subjective characterizations, or legal conclusions.") (citations omitted); *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) ("a court need not

credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss") (citations omitted); *Fisher Bros. Sales, Inc. v. United States*, 46 F.3d 279, 286 (3d Cir. 1995) ("the fact that we must accept the plaintiffs' version of the facts as true does not mean that we must accept the plaintiffs' *characterization* of those facts") (emphasis in the original).

Even a cursory comparison of the '329 patent and the '685 application reveals that there is nothing false about Teva USA arguments. As explained above, the beagle study in the '329 patent has nothing to do with the studies recorded in the '685 application. While the beagle study in the '329 patent sought to study esophageal tissue damage, the studies described in the '685 application are bioequivalence studies that sought to determine how much drug is absorbed. These studies have entirely different purposes and fundamentally different designs; the fact that both studies involve beagles does not make them the same study, and Merck knows it.[7] Teva USA's principal criticism of Merck's study was that it did not model human clinical experience, and therefore was not germane to what happened to patients who actually took the drug. Merck's experts agreed with this assessment. (D.I. 10, Ex. D at 45-46.) There is nothing

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[7] Merck's excerpt from the deposition testimony of a Teva USA expert witness in the risedronate case does not support its argument that Merck's and Teva Ltd.'s studies are "comparable." (D.I. 9 at ¶ 48.) Merck asked Dr. Markowitz whether in the Teva Ltd. experiments the alendronate was administered in accordance with the instructions that Merck provides to human patients. Dr. Markowitz said that it was not administered that way; instead, it was mixed with dog food. The only "comparable" aspect of Merck's and Teva Ltd.'s studies is that neither one administers alendronate to beagles exactly as it is administered to humans. This testimony confirms that Merck's study does not model human clinical experience, as Teva USA correctly argued in the prior litigation.

false about Teva USA's prior arguments and this Court need not accept Merck's unsupported and conclusory allegations to the contrary.

C. Merck Conclusory and Speculative Allegation that this Court or the Federal Circuit Was Deceived Should Not Be Credited

Merck's allegations that "the evidence would have affected the ultimate outcome of the FOSAMAX® once-weekly case" (D.I. 9 at ¶ 24) and that Teva USA's "false representations affected the outcome of the FOSAMAX® once-weekly case because they were relied upon by at least the Federal Circuit in rejecting Merck's beagle studies" (D.I. 9 at ¶ 53) are not allegations of specific facts that if true would demonstrate that the this Court or the Federal Circuit was actually deceived. Merck's conclusory and speculative allegation need not be credited. *See Papasan*, 478 U.S. at 286; *General Motors*, 263 F.3d at 333; *Morse*, 132 F.3d at 906; *Fisher Bros.*, 46 F.3d at 286.

The facts as set forth in the complaint do not support a finding that the district court was deceived. The district court never commented on the merits of Merck's beagle experiments. Moreover, Merck won in the district court because the court *rejected* Teva USA's arguments on the merits. Merck makes no attempt to explain how the court could be deceived by Teva USA and yet rule in favor of Merck.

Moreover, the Federal Circuit simply noted that Merck's experiment had been "discredited at trial and disregarded by the district court." (D.I. 10, Ex. I at 1374.) The Federal Circuit's observation was certainly fair, as the testimony of Merck's witnesses, which is included in an exhibit to Merck's complaint, demonstrates. (*Id.*, Ex. D at 45-46.) The Federal Circuit may have relied on that testimony, not Teva USA's "false" representations, in invalidating the asserted claims of the '329 patent.

At most, Merck's allegations reflect the fact that Teva USA's attorneys successfully argued their version of the facts and their theory of the law of obviousness. That the Federal Circuit resolved the issues in Teva USA's favor does not mean that Teva USA committed a fraud. *See King v. First American Investigations, Inc.*, 287 F.3d 91, 95-96 (2d Cir. 2002) (finding that the plaintiff's allegations that the defendant committed fraud on the court amounted to nothing more than complaining that the plaintiff disputed the defendant's version of the law and facts and thus were insufficient to state a claim for fraud on the court).

D. Merck's Complaint Shows that Merck Could Have Made the Argument It Alleges Was Concealed

Merck's own complaint includes facts sufficient to defeat its claim. It shows that the impeachment argument that Teva USA allegedly concealed was in fact available to Merck at all relevant times.

After trial, Merck successfully moved to add Teva Ltd.'s '006 patent to the trial record (Merck's motion is D.I. 10, Ex. K, and the '006 patent is Ex. A to that motion.) The '006 patent discloses in Example 13 the same type of beagle bioavailability study that is described in the '685 application. (*Compare* D.I. 10, Ex. K, at Ex. A, col. 14, ll. 16-23 *with* D.I. 10, Ex. J. at 8.) If Teva Ltd.'s use of beagles as a test animal impeaches Teva USA's criticisms of Merck, then Merck had the ammunition to make that argument before the district court, the Federal Circuit, and the Supreme Court, and would have done so. However, Merck *never* mentioned the beagle study disclosed in the '006 patent, much less attempted to undermine Teva USA's arguments with it. That Merck did not do so demonstrates the bankruptcy of its current complaint. Because Merck's allegations about the "concealed" impeachment argument are contradicted by Merck's possession

and knowledge of the '006 patent, this Court need not accept Merck's allegations as true. *Rozsa*, 187 F. Supp. 2d at 128 ("When allegations contained within the complaint are contradicted by documents attached to the complaint, the documents control, and the Court need not accept the allegations contained within the complaint as true.")

Thus, the beagle studies in the '685 application do not contradict Teva USA's arguments at trial, as Merck clearly recognized at the time, and there is no evidence that any court was deceived by Teva USA's actions. Merck's allegations that it did not have an opportunity to impeach Teva USA's arguments relating to Merck's beagle experiments are made in bad faith and cannot support an equitable claim of "fraud upon the court" under Rule 60(b).

* * *

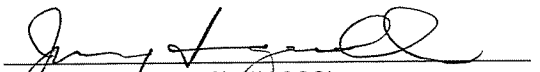
CONCLUSION

For the foregoing reasons, Teva USA's motion to dismiss Merck's first amended complaint for failure to state a claim upon which relief should be granted and the case dismissed.

Dated: June 23, 2006

Respectfully submitted,

YOUNG CONAWAY STARGATT & TAYLOR, LLP



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CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that on June 23, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send e-mail notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on June 23, 2006, I caused a copy of the foregoing document to be served on the above-listed counsel of record by e-mail [mgraham@mnat.com] and hand delivery, and on the following non-registered participants in the manner indicated below:

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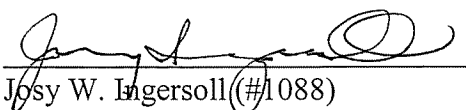

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	:	
Plaintiff,	:	
v.	:	Civil Action No. 01-48 JJF
TEVA PHARMACEUTICALS USA, INC.,	:	
Defendant.	:	

RULE 16 SCHEDULING ORDER

The parties having satisfied their obligations under Fed. R. Civ. P. 26(f), and the Court having conducted a scheduling conference pursuant to Fed. R. Civ. P. 16 and D. Del. LR 16.2(a) and (b),

IT IS ORDERED that:

1. **Pre-Discovery Disclosures.** The parties will exchange by January 5, 2002, the information required by Fed. R. Civ. P. 26(a)(1) and D. Del. LR 16.2.

2. **Joinder of other Parties.** All motions to join other parties shall be filed on or before April 15, 2002.

3. **Discovery.**

(a) All fact discovery shall be commenced so as to be completed by September 20, 2002.

(b) Maximum of 50 interrogatories by each party to any other party.

(c) Maximum of 50 requests for admission by each party to any other party.

(d) Maximum of 25 depositions by plaintiff(s) and 25 by defendant(s).

(e) Reports from retained experts required by Fed. R. Civ. P. 26(a)(2) are due from the party with the burden of proof by October 4, 2002; rebuttal reports by November 8, 2002; Expert discovery shall be completed by December 6, 2002.

(f) **Discovery Disputes.** Any discovery dispute shall be submitted to the Court pursuant to Fed. R. Civ. P. 37. During the course of discovery each party is limited to two (2) Rule 37 motions.

4. **Amendment of the Pleadings.** All motions to amend the pleadings shall be filed on or before April 15, 2002.

5. **Case Dispositive Motions.** Any case dispositive motions, pursuant to the Federal Rules of Civil Procedure, shall be served and filed with an opening brief on or before December 20, 2002. Briefing shall be pursuant to D. Del. LR 7.1.2. No case dispositive motion may be filed more than ten (10) days from the above date without leave of the Court.

6. **Applications by Motion.** Any applications to the Court shall be by written motion filed with the Clerk of the Court in compliance with the Federal Rules of Civil Procedure and the Local Rules of Civil Practice for the United States District

Court for the District of Delaware (Amended Effective January 1, 1995). Any non-dispositive motion shall contain the statement required by D. Del. LR 7.1.1.

7. **Pretrial Conference.** A Pretrial Conference will be held on Friday, February 7, 2003 at 10:00 a.m., in Courtroom No. 6A on the 6th Floor, Boggs Federal Building, Wilmington, Delaware. The Federal Rules of Civil Procedure and Rule 16.4 of the Local Rules of Civil Practice for the United States District Court for the District of Delaware (Amended Effective January 1, 1995) shall govern the pretrial conference.

8. **Trial.** Trial will commence at 9:00 a.m. on Tuesday, March 4, 2003, in Courtroom No. 6A on the 6th Floor, Boggs Federal Building, Wilmington, Delaware.

December 6 2001
DATE

Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC Defendant.	C.A. No. 01-048-JJF (Consolidated) ~~CONFIDENTIAL~~ ~~FILED UNDER SEAL~~

MERCK'S MOTION TO COMPEL
PRODUCTION OF DOCUMENTS AND THINGS

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November 12, 2002

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC Defendant.	C.A. No. 01-048-JJF (Consolidated) ~~CONFIDENTIAL~~ ~~FILED UNDER SEAL~~

MERCK'S MOTION TO COMPEL
PRODUCTION OF DOCUMENTS AND THINGS

Merck & Co., Inc. ("Merck") hereby moves pursuant to Fed. R. Civ. P. 37 (a) for an order compelling Teva Pharmaceuticals USA, Inc. ("Teva") to conduct a proper search for documents responsive to Merck's document requests and to produce those documents promptly. It has now become evident that Teva has failed to search for and produce documents of numerous employees, including key personnel who worked on the project team for the generic product it seeks to market.

MERCK'S ONCE-WEEKLY FOSAMAX®

This patent infringement case involves Merck patents covering the continuous oral administration of alendronate sodium on a once-weekly dosing schedule which cover Merck's highly successful once-weekly FOSAMAX®. FOSAMAX®, approved by the Food and Drug Administration ("FDA"), is used for the prevention and treatment of the debilitating disease osteoporosis. Teva has submitted to the FDA an Abbreviated New Drug Application ("ANDA") No. 75-710 to obtain approval to market generic versions of once-weekly FOSAMAX® prior to the expiration of Merck's patents.

TEVA'S INSUFFICIENT DOCUMENT SEARCHES

Merck has pursued discovery of Teva's decision to market a generic version of Merck's once-weekly FOSAMAX® and its work to implement that decision. Merck early on served basic document requests, and has now taken several depositions of Teva employees involved in that process.

Teva's document production in response to Merck's document requests was scant, only about 4,900 pages.[1] Merck has repeatedly asked that Teva provide additional documents, such as documents reflecting Teva's own conclusions on the commercial success of once-weekly FOSAMAX® and Teva's analysis of the market for a generic version. The commercial success of once-weekly FOSAMAX® is relevant to rebut Teva's assertions that this inventive idea was obvious.[2] But Merck's inquiries about Teva's facially questionable production have met only with unelaborated assertions of Teva's outside counsel that Teva's searches were "thorough" and that "Teva has produced all responsive documents to Merck."

Teva's outside counsels' representations are simply not correct, as is now abundantly clear from several depositions of Teva witnesses whose files were not adequately

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[1] Merck served its First Requests for Production on March 19, 2002. Teva responded on April 19, 2002 (Exhibit A), and produced about 1,790 pages of documents in early June, 2002 (Exhibit B). The other 3,000 pages of documents were previously produced by Teva in the prior litigation between Merck and Teva. Teva has also produced to Merck approximately 2,310 pages of documents that it obtained from subpoenas of third parties.

[2] Teva has raised the affirmative defense that Merck's patents-in-suit are invalid for obviousness over the prior art under 35 USC § 103. To rebut this defense, Merck will present evidence on the commercial success of once-weekly FOSAMAX®. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966) (commercial success is a secondary consideration negating obviousness). *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983); *see also Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986) ("all relevant evidence going to the issue of obviousness/nonobviousness, which includes properly presented evidence on

(Continued. . .)

searched, or searched at all, and from Teva documents revealing that other documents, which have not been produced, must exist. Moreover, counsel's assertions were not based on first-hand knowledge. It turns out that it is in-house counsel who searched for documents.

On September 6, 2002, Teva produced for deposition its first witness, Deborah Jaskot, Teva's Executive Director of Regulatory Affairs, one of only three Teva employees listed in Teva's initial disclosures under Rule 26(a). In response to Merck's questions about documents in her personal files and litigation searches of those files, Ms. Jaskot testified that she is in possession of many relevant documents and folders that were never searched.

In particular, Ms. Jaskot testified that she possesses paper and electronic files (Exhibit C at 142, 146-147), including five years' worth of meeting minutes (*id.* at 151-152), and that Teva maintains a "central ANDA file" (*id.* at 147), marketing forecasts for alendronate sales (*id.* at 123), and internal routing sheets for draft documents, including drafts of documents relating to ANDA 75-710 (*id.* at 47-52). The volume and variety of these documents do not appear in Teva's document production. Ms. Jaskot also testified that, while she recalled producing documents from her personal files for the earlier lawsuit between the parties, she does not recall producing documents in connection with the current lawsuit initiated nearly two years later (*id.* at 148-149).

Following that deposition, Merck wrote to Teva's counsel, detailing the deficiencies in Teva's document production and requesting that Teva's employees' files, including those of Ms. Jaskot, be searched (Exhibits D, E). In response, Teva's counsel, Danae

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(. . . continued.)

> secondary considerations must [be] considered prior to reaching a conclusion on obviousness/nonobviousness").

Schuster, on October 8, 2002 produced, without explanation or response to Merck's specific inquiries, 14 pages of documents purportedly collected from Ms. Jaskot's files (Exhibit F). In a follow-up teleconference, Ms. Schuster informed Merck that the search for the documents described in Merck's letters had been handled entirely by in-house counsel for Teva, and that she had made several requests to Teva's in-house counsel for the documents described in Merck's letters. She further said that the only documents in-house counsel had produced were the 14 pages. When Merck asked about the files of the many recipients listed on these documents, counsel simply reiterated that the 14-page supplemental production from Teva's in-house counsel had addressed Merck's concerns.

After this teleconference, Ms. Schuster by letter dated October 9 produced the most recent version of Teva's package inserts (created in June 2002), without explanation of why Teva had withheld them for four months (Exhibit G). Counsel then asserted simply that, "[w]ith respect to your concern about Teva's document production, all additional responsive documents have now been produced" (*id.*). Despite that representation, however, two weeks later Teva produced without explanation an additional 25 pages at the deposition of its employee Christopher Pelloni on October 23, 2002. Notably, Mr. Pelloni could not remember even the most basic of details about any searches for documents responsive to Merck's requests for production (Exhibit I at 5-11.)

Merck again followed up and asked about the searches of Mr. Pelloni's files and all other employees involved in the alendronate project (Exhibit H). Ms. Schuster called on November 1, 2002 to say only that Teva had purportedly searched for and produced all responsive documents from Mr. Pelloni, and that Teva would provide a response to the rest of Merck's concerns by the end of the day on November 4, 2002 (which we never received).

TEVA DOCUMENTS NOT FOUND IN THE PRODUCTION

Among the 14 pages produced on October 8, 2002 were minutes of two Teva meetings where alendronate was discussed (Exhibit F, T007106 and T007110). These documents went to as many as 28 people who attended the meetings or received the agendas. Teva has not produced, however, any documents from any of these people other than a few purportedly collected from the two Teva employees Merck has deposed, Ms. Jaskot and Mr. Pelloni. It is virtually certain that at least some of the other 26 employees possess other documents responsive to Merck's requests. Furthermore, Ms. Jaskot testified that she took notes at meetings, and that other Teva employees attending these meetings probably took notes (Exhibit C at 128-129). Teva's production of a mere 14 pages cannot possibly reflect all the documents of all relevant Teva employees.

Indeed, Christopher Pelloni testified that the one Teva employee who should be most familiar with Teva's considerations in filing its ANDA is Ms. Anne Payne, who chairs Teva's "product identification team" ("PIT") for alendronate and generates sales forecasts for the prospective generic forms of alendronate and updates to those forecasts (Exhibit I at 39, 40, 120-129). Clearly, Ms. Payne, who is an identified recipient of the minutes, is likely to possess important documents. Yet, Teva has evidently not produced a single document from her files.

The documents Teva has failed to produce relate, *inter alia*, to the commercial success of once-weekly FOSAMAX® in the treatment and prevention of osteoporosis. For example, requests for production nos. 6, 10-14, 16, 17, 43-48 relate to Teva's decision to file ANDA 75-710, Teva's business practices relating to the decision to file ANDA 75-710, and Teva's analysis of the market for the administration of alendronate sodium once per week (Exhibit A.).

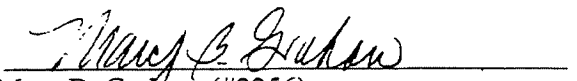
Teva has not produced other important documents, including, *inter alia*, internal and external correspondence relating to ANDA 75-710, internal correspondence between members of Teva's committees and teams, routing sheets containing comments pertaining to ANDA 75-710, all of Ms. Jaskot's paper and electronic files relating to internal committees and teams, documents from Teva's "central ANDA file," and documents from Teva's marketing department including alendronate packaging and marketing forecasts. Considering the number of Teva employees who have received documents relating to alendronate sodium, Teva's failure to search for responsive documents, Teva's miniscule production, and Teva's lack of a document retention policy dictating destruction of documents, Teva's assertion that "all additional responsive documents have been produced" is facially unsupportable.

THE RELIEF NEEDED

Teva's nominal attempts to comply with its discovery obligations and respond to Merck's concerns appear to be primarily limited to searches of (some of) one or two employee files conducted by in-house counsel. Merck submits that Teva should be ordered immediately to produce all responsive documents. Moreover, in view of the testimony of Teva's witnesses and the lack of production of known documents from known Teva employees, the blind reliance of outside counsel upon in-house counsel to conduct searches for documents is clearly insufficient.

Merck requests that Teva be required immediately to conduct a full search for documents, and in view of the history of inadequate production, that Teva's outside counsel conduct the search.

MORRIS, NICHOLS, ARSHT & TUNNELL



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November 12, 2002
318885

CERTIFICATION PURSUANT TO LOCAL RULE 7.1.1

Pursuant to Local Rule 7.1.1, I hereby certify that counsel for Merck has made a reasonable effort to reach agreement with opposing counsel on the matters described in the motion to compel, and that the parties were unable to reach any such agreement.

Mary B. Graham

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 01-048 (JJF)
	)	
TEVA PHARMACEUTICALS USA, INC., and	)	
	)	
Defendant.	)	
	)	

TEVA PHARMACEUTICALS USA'S
RESPONSE TO MERCK'S FIRST SET OF DOCUMENT REQUESTS (1-60)

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Teva responds to Merck's First Set of Document Requests as follows.

Each response is subject to all objections as to competence, relevance, materiality, propriety and admissibility, and to any and all other objections on any grounds that would require the exclusion of any statements contained herein if such responses were asked of, or statements contained herein were made by, a witness present and testifying in court, all of which objections and grounds are expressly reserved and may be interposed at the time of the trial.

The following responses are based upon information and writings currently available and located by Teva and the responses given herein are without prejudice to Teva's right to supplement or to revise these responses if further investigation or discovery so indicates.

Teva's responses shall not be deemed to constitute admission (i) that any particular document or thing exists, is relevant, non-privileged, or admissible in evidence, or (ii) that any statement or characterization in Merck's Document Requests is accurate or complete. In

addition, willingness to produce documents in response to any particular request is in no way a concession that such documents exist, or that any such documents are within Teva's possession, custody or control.

GENERAL OBJECTIONS

Teva's specific responses to all Merck's document requests are subject to the following General Objections, which are incorporated by reference in each response.

General Objection 1

Teva objects to each document request that is inconsistent with or seeks to impose an obligation beyond that required by the Federal Rules of Civil Procedure taken together with the Local Rules of the District of Delaware.

General Objection 2

Teva objects to the production of any documents or things which are subject to the attorney-client or joint defense privilege or work product immunity. In due course, following a completion of production of documents, Teva will provide a log of documents withheld from discovery on the grounds of attorney-client privilege, work product immunity, or both ("Privileged Document Log"), in exchange for such a log from Merck. Any inadvertent disclosure of such information shall not be deemed a waiver of the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity.

General Objection 3

Teva objects to the identification or production of any documents or things dated or prepared after the filing date of the Complaint in this action as being overly broad and unduly burdensome.

General Objection 4

Teva objects to each document request that is vague, indefinite, overly broad, unduly burdensome, and/or oppressive because the burden on Teva to search for, gather and produce such documents, if any, far outweighs the relevancy of such documents, nor are such documents likely to lead to the discovery of admissible evidence.

General Objection 5

Teva objects to each request to the extent it seeks production of "all documents" responsive to the requested categories on the grounds that such request is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections, Teva will use reasonable diligence to locate documents in its own files, based on an examination of those files reasonably expected to yield responsive documents, or summary information to the extent it is available. As used in these responses, the phrase "all documents," or phrases of similar import, should be understood to mean those documents Teva and its counsel were able to locate using reasonable diligence and judgment concerning the whereabouts of responsive documents, or a summary of those documents.

General Objection 6

Teva objects to each document request to the extent it seeks the identification or production of documents or things that are in the public domain and therefore of no greater burden for Merck to obtain than for Teva.

General Objection 7

Teva objects to each document request to the extent it seeks the identification or production of any and all documents and things that are otherwise producible but which contain confidential or proprietary information, except as provided by the District of Delaware local rules

or pursuant to a Protective Order entered in this case.

General Objection 8

Teva objects to the production of the following categories of documents on the grounds that the requests seeking these categories are overly broad, unduly burdensome, and not relevant to the subject matter of this litigation nor reasonably calculated to lead to the discovery of admissible evidence: (I) documents filed in this action and copies of communications between attorneys in this litigation; (ii) documents relating to settlement negotiations; (iii) duplicative or cumulative documents; and (iv) documents already in the possession of Merck.

General Objection 9

Teva objects to each document request to the extent it seeks the identification or production of third party documents that are covered by a third-party confidentiality agreement.

General Objection 10

Teva reserves the right to mask or delete materials from any document or thing that it produces to the extent that such materials are not responsive to any of Merck's requests, not relevant to the subject matter of this action, or not reasonably calculated to lead to the discovery of admissible evidence. Teva also reserves the right to mask or delete materials that are protected from disclosure by the attorney-client privilege, attorney work-product doctrine and/or otherwise immune from discovery.

General Objection 11

Teva objects to each document request to the extent it seeks the identification or production of any document relating to any FDA filing other than ANDA No. 75-710. Teva further objects to each document request to the extent it seeks identification or production of documents relating to ANDA No. 75-710 that are not relevant to this action.

General Objection 12

Teva objects to each document request to the extent it seeks the identification or production of documents relating to any biphosphonate other than the weekly dose forms of alendronate that are the subject of Teva's October 23, 2000 and August 20, 2001 amendments to ANDA No. 75-710 .

General Objection 13

Teva objects to each document request to the extent it seeks information relating to Teva's activities outside the United States, including legal proceedings or any efforts to seek marketing approval in a country other than the United States.

General Objection 14

Teva objects to each document request to the extent it seeks information relating to U.S. Patent Nos. 5,358,941, 5,681,590, 5,849,726, 6,008,207 and 6,090,410. Merck has withdrawn U.S. Patent No. 5,681,590 from this lawsuit, and has indicated it may withdraw U.S. Patent Nos. 5,358,941, 5,849,726, 6,008,207 and 6,090,410 from this lawsuit as well. If Merck decides not to withdraw these patents, Teva will withdraw this objection.

General Objection 15

Teva objects to each document request to the extent it seeks information relating to the manufacture of any of the ingredients in the alendronate formulations that are the subject of ANDA No. 75-710.

General Objection 16

Teva objects to definition I as overly broad to the extent it includes entities beyond Teva Pharmaceuticals, USA. For purposes of the document request, responsive documents in the possession, custody or control of Teva Pharmaceuticals, USA will be produced.

General Objection 17

Teva objects to definition BB, except for purposes of the document request

General Objection 18

Teva objects to the use of the term "defendants" in each of the document requests in which it appears because it is confusing. There is only one defendant in this lawsuit, Teva Pharmaceuticals U.S.A., and Teva will interpret the term accordingly.

General Objection 19

Teva objects to the use of the term "formulation [s]" in each of the document requests in which it appears because it is ambiguous. Teva will interpret this term to mean pharmaceutical formulations, i.e. active ingredients mixed with a pharmaceutically acceptable carrier.

General Objection 20

Teva objects to the use of the term "Defendants' certification" in each of the document requests in which it appears because it is confusing and ambiguous. Teva will interpret this term to mean the Teva's certifications relating to the weekly alendronate sodium product that is the subject of ANDA No. 75-710.

General Objection 21

Teva objects to each of the document requests to the extent they seek documents that have been produced in *Merck v. Teva*, Civ. Action No. 00-035 (JJF). By agreement of the parties, documents produced in that lawsuit will be deemed produced in this lawsuit.

RESPONSES TO DOCUMENT REQUESTS

Document Request No. 1

All opinions, legal or otherwise, relating to the validity, invalidity, infringement, non-infringement, enforceability, non-enforceability, liability, or license (either express or implied) to Defendants for any of the patents-in-suit or any other affirmative defense.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 2

All documents and things, including correspondence with counsel, relating to the validity, invalidity, infringement, non-infringement, enforceability, non-enforceability, liability, or license (either express or implied) to Defendants for any of the patents-in-suit or any other affirmative defense.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 3

All documents and things relating to patent clearances, freedom to operate opinions or other mechanisms to avoid infringement or willful infringement by Defendants of any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 4

All opinions, legal or otherwise, relating to the validity of the patent term extension or the patent term restoration of the '077 patent.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 5

All documents and things, including correspondence with counsel, relating to validity of the patent term extension or the patent term restoration of the '077 patent to Defendants.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 6

All documents and things relating to any policies or practices of Defendants concerning patent clearances, freedom to operate opinions or other mechanisms to avoid infringement or willful infringement by Defendants of the patents of others.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 7

All Abbreviated New Drug Applications filed by Defendants with the FDA for alendronate formulations or other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 8

All supplements and amendments to Abbreviated New Drug Applications filed by Defendants with the FDA for alendronate formulations or other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 9

All documents and things relating to or constituting correspondence or other communications, including but not limited to draft documents and correspondence, among Defendants and/or between Defendants and/or any other person and any foreign or domestic regulatory agency including, but not limited to, the FDA or a foreign counterpart concerning alendronate or any other pharmaceutically active biphosphonate.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 10

All documents and things relating to the patent certifications made by Defendants as part of an Abbreviated New Drug Application alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 11

All documents and things relating to Defendants' decision to file an Abbreviated New Drug Application alendronate formulations or any other pharmaceutically active biphosphonate formulations, including, but not limited to, the timing of the filing, the cost for the filing, and any cost or benefit analysis.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 12

All documents and things relating to the timing, schedule, timetable or projection of approval of Defendants' Abbreviated New Drug Application for alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 13

All documents and things relating to any labeling, promotion, advertising or claims by Defendants for alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to activities in the U.S. regarding the weekly alendronate sodium product that is the subject of ANDA 75-710 will be produced.

Document Request No. 14

All documents and things relating to Defendants' decision for file a patent certification as part of an Abbreviated New Drug Application for alendronate formulations or any other pharmaceutically active biphosphonate formulation.

Response

See response to request no. 10.

Document Request No. 15

All documents and things relating to FDA notification of "tentative approval"of the 'Abbreviated New Drug Application for Defendants' alendronate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced.

Document Request No. 16

All documents and things relating to the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 17

All documents and things relating to the first awareness of the patents-in-suit by Defendants.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 18

All documents and things created before the filing of this suit concerning or constituting any prior art search relating to any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 19

All prior art that Defendants contend supports an allegation that any claim of the patents-in-suit is invalid.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 20

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are not, and/or will not be, infringed by Defendants.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 21

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are unenforceable.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 22

All documents and things forming the basis of, or relating to, any and all defenses pleaded by Defendants that any claim of the patents-in-suit is invalid.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 23

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as lacking a written description.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 24

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as the specification does not enable the claims.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 25

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as indefinite.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 26

All documents and things forming the basis of, or relating to, Defendants' certification

that any of the patents-in-suit are invalid as lacking utility.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 27

All documents and things forming the basis of, or relating to, Defendants' Certification that any of the patents-in-suit are anticipated by the prior art.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 28

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as obvious in light of the prior art

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 29

All documents and things relating to the April 21, 1997 patent term restoration of the '077 patent under 35 U.S.C. § 156.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 30

All documents related to Defendants' patent certification and Notice of Patent Certification for Abbreviated New Drug Applications for alendronate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced.

Document Request No. 31

All documents and things relating to any legal or administrative proceedings concerning the manufacture, importation, sale, and/or offer for sale of pharmaceutical formulations of alendronate or any other pharmaceutically active biphosphonate in the U.S. by Defendants or any other person.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product that is the subject of ANDA No. 75-710 will be produced.

Document Request No. 32

All documents and things concerning any indemnification and/or insurance provided to, received, or granted by Defendants against or for the infringement of any of the patents-in-suit.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 33

All documents and things relating to Defendants' production or attempted production of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 34

All documents relating to research and development of manufacturing processes for alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 35

All documents and things relating to or comprising communications among Defendants and/or between Defendants and any other person concerning the design, development, testing, structure, function and/or operation of manufacturing facilities for the production of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 36

All documents and things relating to U.S. or foreign lawsuits, pending or previously resolved, or investigations regarding Defendants' production of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 37

All documents and things relating to any manufacture, importation, sale, and/or offer for sale of pharmaceutical formulations of alendronate or any other pharmaceutically active biphosphonate in the U.S. by Defendants or any other person.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 38

All documents and things relating to any supply agreement for alendronate or any other pharmaceutically active biphosphonate.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 39

All documents and things constituting or relating to negotiations between Defendants and suppliers or potential suppliers of alendronate or any other pharmaceutically active biphosphonate.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 40

All documents and things relating to any desire, consideration or need by Defendants to obtain or not obtain a license under any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 41

All documents and things constituting or relating to licenses and/or agreements for alendronate or any other pharmaceutically active biphosphonate among Defendants and/or between Defendants and any other person.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 42

All documents and things related to licensing agreements among Defendants and/or between Defendants and any other person for the production, distribution or sale of alendronate formulations or any other pharmaceutically active biphosphonate formulations

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 43

All documents and things concerning marketing or whether to market alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any

other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 44

All documents and things relating to market share and market potential for alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 45

All documents and things relating to the dollar amounts expended by Defendants or any other person for the promotion of alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 46

All documents and things relating to all forms of promotions for or marketing of alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country by Defendants or any other person.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 47

All documents and things created after January 1, 1993, relating to any market survey, market analysis, sales projections or forecast of customer demand with respect to alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product which is

the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 48

All documents and things relating to any communications to or from Defendants' sales forces, agents, dealers, representatives, distributors, the press, or any news wire service relating to this lawsuit, and/or any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 49

All documents, and things relating to research and development of alendronate and alendronate formulations or any other pharmaceutically active biphosphonate and its formulations.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to the General Objections, responsive documents relating to the weekly alendronate product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 50

Two hundred alendronate tablets for each dosage form produced by Defendants for the

purpose of obtaining FDA approval.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, Teva will produce one hundred tablets of each of the weekly alendronate sodium product dosage forms that are the subject of ANDA No. 75-710.

Document Request No. 51

All documents and things relating to any tests comparing Merck's alendronate product with the alendronate product that Defendants produced.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 52

Any samples of Merck products that contain alendronate or any other pharmaceutically active biphosphonate that have been tested or examined by Defendants or any persons working on their behalf.

Response

Teva objects to this request as overly broad and unduly burdensome and is neither relevant to any issue in this lawsuit nor reasonably calculated to lead to the discovery of

admissible evidence.

Document Request No. 53

All documents and things relating to any testing performed using Merck's alendronate product.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 54

All documents and things relating to Defendants' knowledge of Merck's activities in the research, patenting, development, manufacture, use or sale of any pharmaceutical formulation of alendronate or any other pharmaceutically active biphosphonate.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 55

All documents and things Defendants contemplate introducing at trial.

Response

Teva objects to this request as premature.

Document Request No. 56

All documents and/or things relating to any experts Defendants contemplate calling at trial, including but not limited to the educational and technical training of each expert and any publications authored by such expert.

Response

Teva objects to this request as premature.

Document Request No. 57

All documents and things, including but not limited to organizational charts, showing identity and job titles of employees since January 1, 1993 to the present for all of Defendants' divisions and/or subsidiaries involved in the research, development, production, design, manufacture or sale of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections and the General Objections, documents, documents sufficient to describe Teva's organization to the extent it relates to the weekly alendronate sodium product that is the subject of ANDA No. 75-710 will be produced.

Document Request No. 58

All documents and things setting forth Defendants' document retention and/or destruction policies.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections and the General Objections, responsive documents will be produced.

Document Request No. 59

All documents and things relating to or constituting applications by Defendants to obtain regulatory approval for alendronate or any other pharmaceutically active biphosphonate in a foreign country.

Response

See General Objection 12.

Document Request No. 60

Two grams of each ingredient in the alendronate tablets produced by Defendants for the purpose of obtaining FDA approval.

Response

Teva objects to this request because it is overly broad and unduly burdensome. Subject to this and the General Objections, Teva has already produced a two gram representative sample of the active ingredient in the alendronate product that is the subject of ANDA 75-710 in *Merck*

v. Teva, Civil Action No. 00-035 (JJF) .

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463432

CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that I caused copies of the foregoing document to be served on April 19, 2002 upon the following counsel of record:

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